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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,619	09/08/2003	Richard A. Gambale	B0751/7025	2554
22832	7590	02/09/2005	EXAMINER	
KIRKPATRICK & LOCKHART LLP 75 STATE STREET BOSTON, MA 02109-1808			BAXTER, JESSICA R	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/658,619	GAMBALE ET AL.	
Examiner	Art Unit		
Jessica R Baxter	3731		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 13 January 2005.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-9 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-9 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
    1.  Certified copies of the priority documents have been received.  
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
    3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 01132005.

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Species c in the reply filed on January 13, 2005 is acknowledged. The traversal is on the ground(s) that some of the elected claims read on non-elected embodiments. This is not found persuasive because the non-elected species are still considered to be different embodiments of the invention. All claims will be examined since they appear to read on the elected species.

The requirement is still deemed proper and is therefore made FINAL.

### ***Information Disclosure Statement***

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,984,917 to Fleischman et al.

Fleischman discloses a tissue capturing element comprising an internal tissue contacting portion, an external tissue portion; and a tissue contacting anchor; wherein the internal portion undergoes a shape change, the external portion undergoes a shape change, or the anchor portion undergoes a shape change (FIGS. 16A, 16B, 17, 19, 28, 31A, 31B and 31C). The interior tissue portion of the device, the external portion, and the anchor portion are deformed from the delivery configuration to a secondary configuration (Column 8 lines 38-45).

5. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,997,556 to Tanner.

Tanner discloses a tissue capturing element comprising an internal tissue contacting portion, an external tissue portion; and a tissue contacting anchor; wherein the internal portion (FIG. 45) undergoes a shape change, the external portion undergoes a shape change, or the anchor portion undergoes a shape change (FIGS. 39-45, 49-53). The interior tissue portion of the device, the external portion, and the anchor portion are deformed from the delivery configuration to a secondary configuration (Column 26 lines 26-31 and Column 26 line 61 – Column 27 line 53).

### ***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,071,292 to Makower et al.

U.S. Patent No. 6,736,828 to Adams et al.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 571-272-4691. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica R Baxter  
Examiner  
Art Unit 3731

ANHTUANT. NGUYEN  
PRIMARY EXAMINER

2/7/05

  
jrb